

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS  
REPORTED IN D.D.N.J. NOS. 6901-6960

*Adulteration*, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia or National Formulary), and its strength differed from, or its quality or purity fell below, the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its quality fell below, that which it purported or was represented to possess; and Section 501(d) (2), the article was a drug, and a substance had been substituted wholly or in part therefor.

*Misbranding*, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug and (2), in the case where the article was fabricated from two or more ingredients, the common or usual name of each active ingredient, including the quantity, kind, and proportion of acetophenetidin, atropine, hyoscyne, and hyoscyamine contained therein; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions, or by children, where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(i) (2), the article was an imitation of another drug; Section 502(i) (3), the article was offered for sale under the name of another drug; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof; Section 502(l), the article was composed wholly or in part of a kind of penicillin, streptomycin, or bacitracin, and was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; and Section 503(b) (4), the article was a drug subject to Section 503(b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

*New-drug violation*, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

DRUGS AND DEVICE ACTIONABLE BECAUSE OF POTENTIAL DANGER  
WHEN USED ACCORDING TO DIRECTIONS

DRUG AND DEVICE FOR HUMAN USE

6901. Fem-A-Line. (F.D.C. No. 46054. S. No. 87-083 R.)

QUANTITY: 33 4-oz. btls. and 3½ gals. at Dallas, Tex., in possession of Fem-A-Line Laboratories.

SHIPPED: The ingredients were shipped on various dates between 8-18-59 and 3-9-61, from outside the State of Texas.

LABEL IN PART: (Btl.) "Fem-A-Line A Medicinal Adjunct \* \* \* Contains a Laxative \* \* \* Active Ingredients; Fluid Extract Ergot, Tincture Hydras-

tis, and Tincture Aloe \* \* \* Fem-A-Line Laboratories, 2716 North Henderson Dallas, Texas \* \* \* Directions: Teaspoonful 30 minutes before meals and at bed-time in one-fourth glass of hot water \* \* \* Avoid continuous use" and (reused gal. btl.) "Lactated Pepsin Not NF (the word 'Mixed' was handwritten across the label)."

ACCOMPANYING LABELING: Leaflets entitled "Fem-A-Line An Aid To Nature."

RESULTS OF INVESTIGATION: The article was manufactured by the dealer from ingredients which had been shipped in interstate commerce. Some of the article was bottled and labeled and the remainder was stored in the gallon bottles labeled "Lactated Pepsin (Mixed)."

LIBELED: 8-17-61, N. Dist. Tex.

CHARGE: 502(a)—while held for sale, the labeling contained false and misleading representations that the article was adequate and effective to assist retarded menstruation caused by severe colds or other unnatural suppression of the menses; 502(j)—the article was dangerous to health when used as directed in its labeling; and 503(b)(4)—the article was subject to the provisions of 503(b)(1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 11-1-61. Default—destruction.

**6902. Glass syringes.** (F.D.C. No. 46818. S. No. 18-317 T.)

QUANTITY: 1 doz. 2-cc. glass syringes at Palestine, Tex., in possession of Reynolds Clinic.

SHIPPED: On unknown dates, from outside the State of Texas.

ACCOMPANYING LABELING: Leaflets entitled "The Koch Treatment (Glyoxylide)," "Koch Diet," and "Order Form."

LIBELED: 11-21-61, E. Dist. Tex.

CHARGE: 502(f)(1)—the labeling failed to bear adequate directions for use; 502(f)(2)—the labeling failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health and against unsafe methods of application; and 502(j)—the article was dangerous to health when used with the frequency prescribed, recommended, and suggested in its labeling.

DISPOSITION: 1-5-62. Default—delivered to the Food and Drug Administration.

#### DRUG FOR VETERINARY USE

**6903. Medicated turkey feed (5 seizure actions).** (F.D.C. Nos. 46276, 46422/5. S. Nos. 81-148/9 R, 81-395/9 R, 6-441 T.)

QUANTITY: 20 100-lb bags (crumbles), 310 100-lb. bags and 60 75-lb. bags (pellets), at Millis, Marlboro, Framingham Center, North Andover, and Lanesboro, Mass.

SHIPPED: Between 6-30-61 and 7-31-61, from Oneonta, N.Y., by Elmore Milling Co., Inc.

LABEL IN PART: (Tag) "Elmore Turkey Growing Mash Medicated (1H) \* \* \* Active Drug Ingredients: 4-nitrophenylarsonic acid (Histostat) 0.025% \* \* \* Manufactured by Elmore Milling Company, Inc., Oneonta, N.Y. (Pellets) [or "Crumbles"] [some bags bear another tag reading "Small" or "Pellets"]."

RESULTS OF INVESTIGATION: Examination showed that the article contained more than the declared amount of 4-nitrophenylarsonic acid.